

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
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## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference <b>L0644.70000</b>		Date of mailing (day/month/year) <b>08 SEP 2005</b>
<b>FOR FURTHER ACTION</b> See paragraph 2 below		
International application No. <b>PCT/US04/41830</b>	International filing date (day/month/year) <b>14 December 2004 (14.12.2004)</b>	Priority date (day/month/year) <b>16 December 2003 (16.12.2003)</b>
International Patent Classification (IPC) or both national classification and IPC <b>IPC(7): A61B 1/04 and US Cl.: 600/114</b>		
Applicant <b>LEVEY, JOHN M.</b>		

1. This opinion contains indications relating to the following items:

- |                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input type="checkbox"/>            | Box No. II   | Priority   |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited  |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application   |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application  |

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Linda C.M. Dvorak <i>Liane Dvorak</i> Telephone No. 703-308-2193
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Form PCT/ISA/237 (cover sheet) (January 2004)

Confirmation	Initials
Docketing	<input checked="" type="checkbox"/> <i>LD</i>
<b>12/08/05</b>	

**DOCKETED**  
**SEP 13 2005**

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International application No.

PCT/US04/41830

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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International application No.  
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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-15</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-15</u>	NO
Industrial applicability (IA)	Claims <u>1-15</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-15 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 5,941,815 to Chang.

In regards to claim 1, Change discloses an annular tube 12 having outer 14 and inner 16 surfaces with the inner diameter of the tube sized to permit sliding passage therethrough of the insertion end of an endoscope tube, the annular tube having means 22 for coating the endoscope tube as it passes through the annular tube with a lubricant (see Fig. 1 and Col. 7).

In regards to claim 2, Change discloses a control having an annular flang 20 extending outwardly from the outer surface of the annular tube closer to the proximal than distal end thereof (see Fig. 1)

In regards to claims 3-4, Change discloses a control wherein the coating means 22 comprises a compressible foam member impregnated with a lubricant positioned to engage an endoscope tube as it moves through the control and wherein the inner uncompressed diameter is substantially equal to the outer diameter of an endoscope tube (see Col. 7, Line 55 - Col. 8, Line 5).

In regards to claims 5-8, Change discloses a control having a flange 20 extending outwardly from the annular tube close to the proximal end thereof, to preclude insertion of the control into the body cavity of a patient (see Col. 7, Lines 37-49).

In regards to claims 9-11 and 13, Change discloses a control having a passage 60 for feeding a lubricant into the interior of the annular tube (see Fig. 1 and Col. 9, Lines 13-36). The apparatus of Chang is considered inherently capable of performing the recited method claims (see Col. 9, Line 36 - Col. 10, Line 28).

In regards to claims 12 and 14, Change discloses a control wherein the compressible foam member comprises an annular tube having a major portion of its length coaxial and coextensive with at least portion of the annular tube (see Col. 5, Line 34 - Col. 6 Line 17).

In regards to claim 15, Change discloses a control wherein the control has a means for opening the control along its length (see Figs. 6-8).

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**WRITTEN OPINION OF THE  
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**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

The drawings are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 7 because: poor quality and lack of reference numbers on Figures 6 and 7.

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